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Applicants: Solomon S. Steiner and Bryan R. Wilson

Serial No.: 09/766,362

Art Unit: 1614

Filed: January 19, 2001

Examiner: Not Yet Assigned

For: *DRY POWDER FORMULATIONS OF ANTIHISTAMINE FOR  
NASAL ADMINISTRATION*

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including three (3) pages of Form PTO-1449 and a copy of each document cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
4,151,273	04-24-1979	Riegelman et al.	424/78
4,272,398	06-09-1981	Jaffe	252/316
4,332,721	06-01-1982	Bernini	260/239.57
4,384,975	05-24-1983	Fong	427/213.36
4,861,627	08-29-1989	Mathiowitz.	427/213.31
5,043,280	08-27-1991	Fischer et al.	435/235.1

5,354,562	10-11-1994	Platz et al.	424/489
5,700,471	12-23-1997	End et al.	424/400
5,747,002	05-05-1998	Clark et al.	424/45
5,776,495	07-07-1998	Duclos et al.	424/455
5,780,062	07-14-1998	Frank et al.	424/501
5,800,834	09-01-1998	Spireas et al.	424/451
5,817,343	10-06-1998	Burke	424/489
5,833,891	11-10-1998	Subramaniam et al.	264/7
5,851,453	12-22-1998	Hanna et al.	264/5
5,855,913	05-05-1999	Hanes et al.	424/489
5,874,064	02-23-1999	Edwards et al.	424/46
5,952,008	09-14-1999	Backstrom et al.	424/499
5,352,461	10-04-1994	Feldstein et al.	424/493
5,503,852	05-02-1996	Steiner et al.	424/493
6,071,497	06-06-2000	Steiner et al.	424/45

#### Publications

BENITA, et al., "Characterization of Drug-Loaded Poly(d,l-lactide) Microspheres," *J. Pharm. Sci.* 73:1721-1724 (1984).

KATCHALSKI, et al., "Synthesis of Lysine Anhydride," *J. Amer. Chem. Soc.* 68:879-880 (1946).

KOPPLE, et al., "A Convenient Synthesis of 2,5-Piperazinediones," *J. Org. Chem.* 33(2):862-864 (1968).

KORNBLUM, "Sustained-action tablets prepared by employing a spray-drying technique for granulation," *J. Pharm. Sci.* 58(1):125-27 (1969).

LIM, et al., "Microencapsulation of living cells and tissues," *J. Pharm. Sci.* 70:351-354 (1981).

MATHIOWITZ & LANGER, "Polyanhydride Microspheres As Drug Carriers I. Hot-Melt Microencapsulation," *J. Controlled Release* 5:13-22 (1987).

MATHIOWITZ, et al., "Polyanhydride Microspheres as Drug Carriers. II. Microencapsulation by Solvent Removal," *J. Appl. Polymer Sci.* 35:755-774 (1988).

MATHIOWITZ, et al., "Polyanhydride Microspheres. IV. Morphology and Characterization of Systems Made by Spray Drying," *J. Appl. Polymer Sci.* 45:125-134 (1992).

MATHIOWITZ, et al., "Novel Microcapsules for Delivery Systems," *Reactive Polymers* 6:275-283 (1987).

MATHIOWITZ, et al., "Morphology of Polyanhydride Microsphere Delivery Systems," *Scanning Microscopy* 4:329-340 (1990).

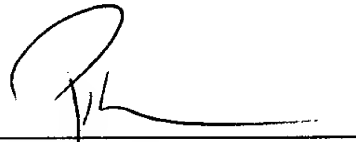
SALIB, et al., "Utilization of Sodium Alginate in Drug Microencapsulation," *Pharmazeutische Industrie* 40(11A):1230 (1978).

SAWHNEY, et al., "Bioerodible Hydrogels Based on Photopolymerized Poly(ethylene glycol)-co-poly( $\alpha$ -hydroxy acid) Diacrylate Macromers," *Macromolecules* 26:581-587 (1993).

### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



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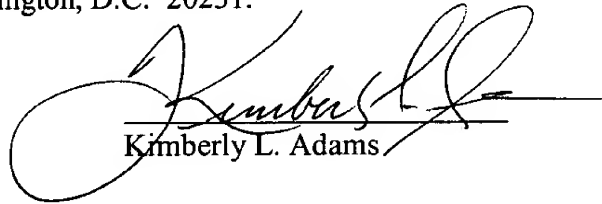
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INFORMATION DISCLOSURE STATEMENT



**Certificate of Mailing under 37 C.F.R. § 1.8(a)**

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: September 20, 2001

  
Kimberly L. Adams